

# EXHIBIT A

**ABSTRACT SUMMARY**

# Effect of Diabetes-Specific Oral Nutritional Supplements on Postprandial Glycemic Response in Adults with Type 2 Diabetes Mellitus

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## Objective:

To determine if a diabetes-specific oral nutritional supplement (DS-ONS) provides improved postprandial blood glucose response relative to a standard ONS in individuals with type 2 diabetes (T2D).

## Methods:

- Randomized, crossover clinical trial which enrolled 14 adults with T2D.
- Participants were randomized to receive isocaloric amounts of DS-ONS (BOOST Glucose Control® Nutritional Drink) or Control (Standard ONS) on separate study days, each one week apart. The DS-ONS was higher in protein, fat, and fiber, and lower in carbohydrates and sugars compared to the control. ^ See Table 1 for nutritional information.
- Blood glucose and serum insulin values were measured at baseline and 10, 20, 30, 60, 90, 120, 150, 180, 210 and 240 minutes after consumption and used to calculate the area under the curve (AUC) as well as peak ( $C_{max}$ ) blood glucose and insulin concentrations for each participant.
- Participants were instructed not to take any diabetes medications before or during the 4-hour study visits.

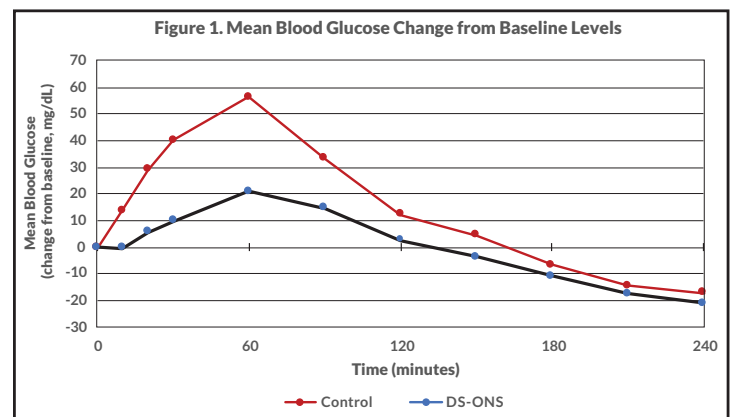
## Results (Figure 1 and Table 2):

- All 14 participants completed the study. Data for two participants were excluded as outliers due to unlikely blood glucose values, leaving 12 individuals included in the analysis (Age:  $61 \pm 6$  years; BMI  $28.1 \pm 5.7$ ; n=7 Female, n=5 Male)
- Glucose: There were no differences in blood glucose levels at baseline ( $p > 0.05$ ). Mean blood glucose AUC and  $C_{max}$  for blood glucose were significantly lower for DS-ONS vs. control ( $p < 0.01$  for all comparisons).
- Insulin:  $C_{max}$  for insulin was significantly lower for DS-ONS vs. control ( $p < 0.01$ ), but there were no differences in insulin AUC, first-phase insulin response ( $AUC_{0-30 \text{ min}}$ ) or insulinogenic index between products.

**Table 1. Nutritional Profile of Control and DS-ONS**

	Control	DS-ONS
Volume, mL	188	237
Calories	190	190
Protein, g	7.9 (17% TE)	16 (33% TE)
Carbohydrate, g	32 (68% TE)	16 (34% TE)
Sugars, g	16	4
Fiber, g	0	3
Fat, g	3.2 (15% TE)	7 (33% TE)

TE = Total Energy



**Table 2. Glucose and insulin responses for Control vs. DS-ONS**

	Control	DS-ONS
Glucose AUC <sub>0-240 min</sub> , mg/dL	3515±5205	100±3484*
Glucose $C_{max}$ , mg/dL	189±48	151±30*
Insulin AUC <sub>0-240 min</sub> , µIU/mL	1773±2213	680±769
Insulin AUC <sub>0-30 min</sub> , µIU/mL	194±224	102±240
Insulin $C_{max}$ , µIU/mL	37±33	19±22*
Insulinogenic Index, µIU/mmol	8.4±8.7	14.2±22.6

Values are mean ± standard deviation; \* $p < 0.01$  vs. control

Pairwise p-values have Bonferroni adjustment for multiple comparisons

## Conclusions:

- DS-ONS attenuated the overall blood glucose response and produced lower postprandial blood glucose peaks compared to a standard ONS.
- Specially formulated DS-ONS can be a useful tool to provide nutritional support as part of an overall diabetes management plan in individuals with T2D.

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^ The original study included separate comparisons of two DS-ONS formulations vs. control. As one formulation is no longer commercially available, this summary was simplified to include only the existing DS-ONS.

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The abstract can be accessed online at:

<https://aspenjournals.onlinelibrary.wiley.com/doi/10.1002/jpen.2095>

